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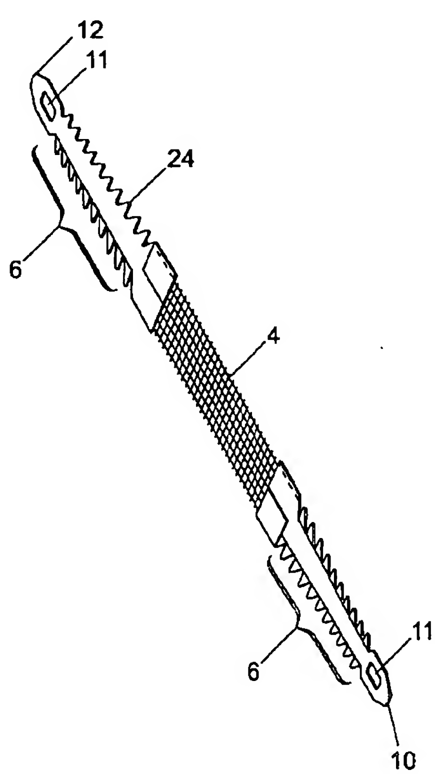

(57) **Abstract:** The present invention relates to a medical implant for example an incontinence tape or sling, a fascial tissue repair sheet, hernia repair sheet, or a prolapse repair sheet which comprises a resilient zone, wherein the resilient zone provides for the resilient extension of the implant in a manner similar to that of soft dynamic body tissue. The implant being limited in its extension in response to physiologically relevant forces such that it does not over extend.

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"Medical Implant"

The present invention relates to medical implants. In particular, but not exclusively, the invention relates to medical implants for use in treating urinary incontinence, fascia repair, including abdominal wall hernia and pelvic floor prolapse.

Urinary incontinence affects a large number of women and, consequently, various approaches have been developed to treat female urinary incontinence. Those skilled in the art will be familiar with approaches ranging from pelvic floor exercises to surgical techniques such as Burch colposuspension and Stamey-type endoscopic procedures in which sutures are placed so as to elevate the bladder neck.

This invention is particularly directed to the improvement of a known procedure in which a sling is positioned loosely under the urethra. Such tape is commonly known as TVT (tension free vaginal tape) and described, for example, in International Patent

Application Nos. WO 97/13465 and WO 96/06567. It is generally understood that this treatment alleviates urinary incontinence by occluding the mid-urethra (for example at a time of raised abdominal pressure by coughing or the like).

To provide a sling loosely under the urethra, using the apparatus and method of the prior art, an incision is made in the anterior vaginal wall and a first needle is passed through the incision, past one side of the urethra, behind the pubic bone, through the rectus sheath and out through the lower anterior abdominal wall. A second needle is passed likewise through the incision, past the other side of the urethra, behind the pubic bone, through the rectus sheath and out through the lower abdominal wall. The needles are separated from their respective insertion tools and also from the mesh or tape such that only the tape and its plastics sleeve are left in the body, passing from a first exit point in the lower abdominal wall, through the rectus sheath, behind the pubic bone, under the urethra, back behind the pubic bone, back through the rectus sheath and out through a second exit point in the lower abdominal wall.

The plastics sleeve is then removed from the tape and the tape adjusted to a suitable tension (such that the tape provides a sling that passes loosely under the urethra, as described above) by manoeuvring the free ends of the tape outside the exit points in the lower abdominal wall whilst the

urethra is held using a rigid catheter inserted therein. The tape is then cut such that it just falls short of protruding from the exit points in the lower abdominal wall. The exit points and the incision in the upper vaginal wall are then closed by sutures.

Whilst highly effective in treating urinary incontinence, this procedure has a number of problems. For example, in order to provide support to the urethra the tape requires to support the urethra during periods of increased abdominal pressure, but if the tape pulls on the urethra with too much force it can lead to difficulty in urinating, discomfort and tissue damage. Tissue damage may occur at the urethra and also where the tape is anchored.

The suitable location of an implant to support the urethra during periods of increased abdominal pressure, but such that the implant does not pull on the urethra during periods of normal abdominal pressure and cause discomfort, is difficult for surgeons to achieve. Conventional tape implants are generally very stretchy and surgeons are required to position the tape in the body such that in use, during periods of normal abdominal pressure, the implant is in a stretched or extended position.

In addition, the requirement that the needles exit the lower abdominal wall is disadvantageous due to the trauma to the patient in this area and the pain

of such abdominal wounds. A further disadvantage is that, as the tape is required to extend from the lower abdomen wall under the urethra and back through the lower abdomen wall, the tape must comprise a relatively large foreign body mass (typically around 25 to 28 cm in length) to be retained within the patient. This can lead to related inflammation, infection translocation, erosion, fistula and such like.

Further details of the apparatus and methods of the prior art are provided in PCT/GB01/04544.

Most of the pain associated with previous procedures, to introduce a surgical implant as described above, is due to the force required to penetrate the tough structures of the abdominal wall or rectus sheath, both of which are highly innervated.

Suitable location of a surgical implant such that it provides support to the urethra, without requiring penetration of the lower abdomen or rectus sheath, would reduce the trauma experienced by the patient. As a greater number of major blood vessels are located in the retropubic space towards the rectus sheath than toward the endopelvic fascia, locating the implant without piercing the rectus sheath minimises the damage to these blood vessels. This reduces the amount of bleeding experienced by the patient.

The present invention overcomes some of the problems associated with medical implants suitable for use in supporting the urethra and / or tissue repair of the prior art.

According to a first aspect of the present invention there is provided a medical implant which comprises a mesh, wherein the mesh is a resilient zone which in use provides for the resilient extension of the implant.

The resilient extension mimics typical physiological elasticity of tissue.

According to a second aspect of the present invention there is provided a medical implant comprising a resilient zone wherein in response to forces up to 20N the resilient zone provides for the resilient extension of the length of the implant by between 1 to 60%.

Maximum physiological abdominal pressures are around 200 mm of Mercury at periods of increased abdominal pressure such as coughing or sneezing. This translates to a physiological force of 20N on implants used to support the urethra or for hernia repair.

According to both aspects of the present invention the resilient zone provides for the resilient extension of the length of the implant by between 5 to 40%.

Tissue typically can be thought of as either having no elasticity, for example a urethra following the formation of adhesions, physiological resilience or elasticity, wherein physiological forces of around 3N to 20N promote resilient stretching of the tissue, or hypermobility or fascial failure. In hypermobility or fascial failure the tissue is capable of over extension and thus is not able to provide support.

The implant of the present invention is not static like many conventional implants for hernia repair. However, the implant of the present invention is not so extensible that it shows 100% extension of its overall length in response to physiological forces. At such forces the implant of the present invention is still able to provide support.

In a preferred embodiment the implant is for use in tissue support or repair.

Preferably the resilient extension of the implant provides the implant with extension similar to that of dynamic bodily tissues, but does not allow the excessive movement observed following fascial failure, for example bladder or urethral hypermobility in stress incontinence or in prolapse or hernia sac protrusion.

Typically the forces applied to tissues during physiological situations such as coughing or sneezing are between 3 to 15 N.

Urethral hypermobility leading to stress incontinence is well known and can be defined using a range of techniques as set out by the International Continence Society.

The inclusion of a resilient zone in a medical implant such that the implant is capable of resiliently stretching in response to forces applied to it, to a limited extent while in the body of a patient, allows a patient to suffer less tissue distortion following implantation of such an implant in comparison to conventional implants.

It can be appreciated that different tissue types for example, skin, muscle, fascia will have different amounts of extension in relation to a particular force. In addition, the amount of force applied may effect the extension or dynamic bodily movement of a particular tissue type. By tailoring the geometric or micro material design of the resilient zone of the implant, different amounts of resilient extension can be achieved.

Preferably the resilient zone of the implant is capable of allowing the resilient extension of at least part of the implant due to the geometric design of the resilient zone.

Resilience determined by geometric design of the resilient zone depends on the arrangement of the material e.g. its shape, cast, mesh construction etc.

The geometric design of the resilient zone may be the shape of the resilient zone, for example, but not limited to, a concertinaed shape, a mesh portion, bowshaped strips of material, etc.

Alternatively, or in addition to a geometric design, the resilient zone of the implant can be capable of allowing resilient extension of at least part of the implant due to the micro material design of the resilient zone.

Micro material design refers to the weave or construction of the material used to form the resilient zone, the type of material of the resilient zone, etc.

More preferably the resilient zone of the implant is capable of allowing the resilient extension of the implant due to a combination of its geometric and micro material design.

In a preferred embodiment the geometric design is a mesh.

Preferably the mesh comprises strands and includes major spaces and pores, the major spaces existing

between the strands and the pores formed within the strands.

More preferably the strands of the mesh are formed from at least two filaments. Preferably the strands are spaced apart to form major spaces of 1.8 to 5 mm. Preferably the strands have a diameter of less than 600μm. The strands may be arranged to form a warp knit diamond or hexagonal net mesh.

In an alternative embodiment the geometric design includes multiple strips of material.

More preferably, in this second embodiment the geometric design includes multiple strips of material arranged into bows, the bows being capable of deforming and providing resilient extension to the implant.

In such an embodiment, when not under tension the strips of material are bow shaped and are arranged such that they form a series of alternate and side by side convex and concave bowshaped strips arranged in the same plane as the implant.

On application of an extending force to the bowshaped strips along their length, the implant can show resilient extension. During extension, the bowshaped portions of the resilient zone are pulled into straight strips, the ends of the bowshaped strips being brought together, enabling extension of the implant. The movement of the strips of material

of the resilient zone of the implant from the resting bowshape into the tensioned straight strips allows the implant to resiliently extend along its length.

On release of the extending force, the straightened strips of material of the resilient zone return to their previous non-extended bowshape causing the implant to resiliently return to its non-extended length.

In a further alternative embodiment, the resilient zone of the implant comprises a concertinaed portion such that the medical implant may extend in a direction substantially perpendicular to the folds of the concertinaed portion.

In a collapsed position the concertinaed portion of the implant is folded up such that the folds of concertinaed portion are brought together such that the implant is folded back upon itself. In an extended position the concertinaed portion is pulled such that the folds of the concertinaed implant are pulled apart from each other such that the material moves toward an unfolded position.

The extent of resilience of the implant will depend on the particular use of the implant.

Preferably resilient extension of the resilient portion of the medical implant occurs when an

extension force of 0.1N to 20N is applied to the implant.

More preferably resilient extension of the resilient portion of the medical implant occurs when an extension force of 1N to 15N, 1N to 5N or 1 to 3N is applied to the implant.

Preferably the implant is constructed from any suitable material. More preferably said material is biocompatible.

Preferably the implant is formed from a synthetic polymer.

Preferably the implant is formed from non-absorbable polymer.

Alternatively, the implant is formed from absorbable material. This enables the implant to be incorporated into the body over time. The implant being absorbed over time into the surrounding tissues. The characteristics of absorbance of the implant, for example the time it takes for the implant to be absorbed, will depend on the material of construction. The material of construction can be chosen to best suit the application of the medical implant.

Preferably the resilient zone of the implant is formed of the same material as other portions of the implant.

Alternatively the resilient zone of the implant is formed of a different material to other parts of the implant.

Medical implants of the invention may include, but are not limited to, incontinence tapes and slings, and meshes, patches and / or implants for use in fascial repair, hernia repair or prolapse repair. Depending on the types and size of the medical implant, the resilient zone may provide different amounts of resilient extension to the implant in one or more defined directions.

In a particularly preferred embodiment the implant is for use in urethra support. Use of an implant to support the urethra can be used to treat stress incontinence.

According to a second embodiment of the present invention, there is provided tape means capable of being fixed such that, in use, the tape means passes under the urethra and, during periods of increased abdominal pressure, the tape supports the urethra, the tape comprising a resilient zone wherein the resilient zone provides resilient extension of at least a portion of the tape.

Preferably the tape is capable of resilient extension in a similar manner to that of dynamic bodily tissue.

More preferably the tape is capable of resilient extension in a similar manner to that of dynamic bodily tissue surrounding and supporting the urethra.

Slings or tapes presently used to support the urethra vary in the extent to which they can be extended along their longitudinal length and do not behave in a similar manner to dynamic body tissue.

"Tension free Vaginal Tape" is very extensible and can be pulled such that it extends from an unstretched length of around 28 to 30 cm by a further 30 cm in length or more.

The ability of TVT to be extended to such an extent is disadvantageous. In situ, such a tape must be extended to its maximum length to ensure that the urethra is suitably supported at times of increased abdominal pressure. During placement of the tape in the body the tape is thus pulled relatively tight under the urethra such that the tape has suitable tensile strength to suitably support the urethra at times of increased abdominal pressure. Thus a conventional implant, in use, is not resilient.

Similarly, in use American Medical Systems SPARC ™ tape is not resilient. This tape, which includes a suture which runs along the length of the tape and prevents the tape extending beyond a defined length, still requires to be pulled relatively tight under the urethra in order that the urethra is suitably

supported at times of increased abdominal strength. The pulling of the implant tight under the urethra to ensure suitable support means that, in use, this tape is not resilient. Thus when located to provide suitable tensile strength, the implant does not resiliently stretch when supporting the urethra at periods of increased abdominal pressure.

As discussed above, when located in the body, a medical implant tape is located around the mid point of the urethra such that space exists between the portion of the tape which passes under the urethra when the urethra is in a rest position, during periods of non-increased abdominal pressure.

During urination, muscles in the wall of the bladder contract, forcing urine out of the bladder and into the urethra and sphincter muscles surrounding the urethra relax. This allows urine to pass out of the body.

Incontinence occurs if the bladder muscles suddenly contract or muscles surrounding the urethra suddenly relax.

Pelvic floor muscles support the bladder and, if these muscles weaken, the bladder can move downward. This causes the bladder to move out of the bottom of the pelvis, e.g. in females, where the condition is most common, towards the vagina. This movement prevents the muscles that ordinarily force the urethra shut from squeezing as tightly as they

should. As a result, urine can leak into the urethra during moments of physical stress such as coughing or sneezing. Stress incontinence also occurs if the muscles that do the squeezing become weakened.

By suitable location of a tape implant to support the urethra at times of increased abdominal pressure, the voiding of urine during moments of physical stress including coughing or sneezing can be minimised. The tape acts to support the urethra by strengthening weakened or damaged muscles, which control urination. The implant may additionally facilitate the repair of damaged tissues.

It is important that the tape is secured such that it can adequately support the urethra during periods of increased abdominal pressure. Typically, during periods of increased abdominal pressure a force of between 3N to 15N will be exerted on the tape by the urethra.

The inclusion of a resilient zone in the tape as described above means the tape will be more suitable for use in supporting the urethra than conventional implants. The tape of the present invention is able to provide sufficient tensile strength to the urethra to support the urethra during periods of increased abdominal pressure and thus prevent incontinence, but has sufficient resilience not to cause or apply unacceptable pulling to the urethra at periods of non-increased (resting) abdominal pressures or increased abdominal pressures.

Discomfort and tissue distortion may therefore be minimised.

Preferably the implant has a maximum tensile strength of around 35N.

Preferably the tape means extends 13% of its overall length at 5N, and 40% of its overall length at 20N.

Preferably the tape extends approximately linearly when increasing force is applied to the tape within the range 1 to 35N.

In contrast TVT typically shows 75% extension of its overall length when a force of 5N is applied and 100% of its overall length when a force of 20N is applied.

The implant of the present invention therefore more closely mimics the elasticity or resilience of the tissues that would normally support the urethra.

This has the advantage that there is less chance of damage to the urethra by the tape.

In addition, the inclusion of a resilient zone in the implant means that there is greater tolerance in locating the implant in the body. This provides a further advantage over the conventional implants, with no or limited resilience, which must be located in a fairly precise position, with little or no tolerance. For example, location of an implant,

wherein the implant has no ability to extend, too far below the urethra will not provide support to the urethra. However, if a conventional implant is positioned such that it pulls too much on the urethra, in a resting position when abdominal pressures are not increased, then the tape will cause discomfort at periods of increased abdominal pressure and possibly problems of voiding urine.

An implant of the present invention need not be placed so accurately, as, due to the resilient stretching of the implant, there will be tolerance in the exact position in which the implant is required to be located to provide suitable support to the urethra.

To date, the tape of the present invention has been used in 12 patients and the 12 patients no longer suffer from stress related incontinence.

Preferably the implant tape means comprises at least one suspensory portion and at least one and urethra support portion.

In a first preferred embodiment the resilient zone is located in the urethra support portion. Preferably the resilient support portion is a resilient mesh.

In a second embodiment the resilient zone is located in a suspensory portion of the tape means.

Preferably the resilient zone provides for the longitudinal length of the tape to be resiliently extended by around 1 to 20 mm during application of physiological forces of between 3N to 20N along the longitudinal length of the tape.

More preferably the resilient zone provides for the longitudinal length of the tape to be resiliently extended by 5 to 10 mm during application of physiological forces of between 3N to 20N along the longitudinal length of the tape.

Preferably the tape resiliently extends between 5% to 60% of its overall length on application of a force of 5N along the longitudinal length of the tape. More preferably the tape resiliently extends between 10% to 30% of its overall length on application of a force of 5N along the longitudinal length of the tape. In a further preferred embodiment the tape resiliently extends between 10% to 15% of its overall length on application of a force of 5N along the longitudinal length of the tape.

Preferably the tape resiliently extends between 5% to 60% of its overall length on application of a force of 20N along the longitudinal length of the tape. More preferably the tape resiliently extends between 10% to 60% of its overall length on application of a force of 20 N along the longitudinal length of the tape. In a further preferred embodiment the tape resiliently extends

between 10% to 45% of its overall length on application of a force of 20N along the longitudinal length of the tape.

According to a further embodiment of the present invention there is provided a medical implant for use in hernia repair, fascial repair or vaginal prolapse.

Preferably the implant is sheet-like in form.

The implant may be a relatively flat square, circle or any suitable shape of material which includes a resilient portion.

Preferably the implant is a mesh, textile patch or dressing.

In this embodiment, preferably the resilient zone provides for the resilient extension of the implant in at least one defined direction such that in said direction the implant is capable of resiliently increasing in length by 1 – 60% of the length of the implant in said direction.

Preferably the implant resiliently extends between 5% to 60% of its length in a defined direction on application of a force of 5N across the implant. More preferably the implant resiliently extends between 10% to 30% of its length in a defined direction on application of a force of 5N across the implant. In a further preferred embodiment the

implant resiliently extends between 10% to 15% of its length in a defined direction on application of a force of 5N across the implant.

Preferably the implant resiliently extends between 5% to 60% of its length in a defined direction on application of a force of 20N across the implant. More preferably the implant resiliently extends between 10% to 60% of its length in a defined direction on application of a force of 20 N across the implant. In a further preferred embodiment the implant resiliently extends between 10% to 45% of its length in a defined direction on application of a force of 20N across the implant.

The direction of extension can be defined in the implant by use or placement of geometrical or micro material designs in the implant. A force across the implant may be a force in the plane of the implant or a force normal to the plane of the implant.

The resilient portion may be located at any suitable position in the implant.

In a preferred embodiment the resilient zone is located around the perimeter of the material to allow extension in any direction.

The location of a resilient zone at a particular point in the implant is advantageous as it can limit the resilient extension of the implant to particularly defined directions. Further,

particular areas of the implant can be designed to provide more support than other areas of the implant.

Preferred features for each aspect of the invention are as for each of the other aspects mutatis mutandis.

Embodiments of the present invention will now be described, by way of an example only, with reference to the accompanying drawings, in which;

Figure 1 shows a medical implant for use in treating urinary incontinence;

Figures 2A and 2B show medical implants for use in treating fascia repair;

Figure 3 shows an alternative medical implant for use in treating urinary incontinence;

Figure 4 shows a graph of the extension of an implant of the present invention with respect to load; and

Figure 5 shows a graph of the extension of Tension free Vaginal Tape with respect to load.

As shown in figure 1, the medical implant is a flat tape 2 which has a supporting zone 4 interposed between two fixing zones 6, the fixing zones comprising means to achieve multilayer fixation in

the retropubic space such that in use the supporting zone 4 is positioned loosely under the urethra. Apertures 11 extend through tape at first 10 and second 12 ends of the tape. These apertures are of suitable dimension to allow an introducing tool, used in the placement of the fixing region of the implant in the retropubic tissues, to be passed through.

In one embodiment the medical implant is 4 cm in length, 1 cm in width and 200 µm in thickness. The supporting zone is approximately 4 cm in length such that in use this zone can pass under the urethra.

The resilient zone of the tape implant shown in figure 1 is provided in the supporting zone by a mesh portion which, in use, is located under the urethra. This mesh portion can resilient extend following the application of forces in the range 3N to 20N such that urethra is supported. This support is more similar to that as provided by dynamic bodily tissue and thus minimises damage caused to the urethra.

The tape as shown in figure 1 does not require to be entirely flat and may be curved in one or more directions for example to aid insertion of the tape or to ensure that the fixing means do not interfere with element contained in the retropubic space such as the bladder.

A further advantage is that as the tape shows resilient extension along its length when force is applied to the tape then less force is transmitted along the tape to the regions of the tissue in which the implant is fixed and thus tissue damage at these areas is minimised.

By comparison of the graphs as shown in figures 4 and 5 it is clear that the extension of an implant of the present invention in comparison to Tension free Vaginal Tape (TVT) is different. In particular, it is clear the implant of the present invention extends approximately linearly as load is increased whereas TVT shows substantial extension at low loads. Testing of TVT has shown that the length of TVT extends by around 75% at 5N and 100% at 20N. In contrast this embodiment of the present invention extends in the length by 13% when a force of 5N is applied and 40% when a force of 20N is applied.

With a sample width of 1 cm and length of 7.5 cm comparative studies of TVT and an implant of the present invention determined the modulus of TVT to be 0.05N per % elongation at 10% elongation, 0.067N/% at 20% and 0.082N/% at 30%. This means that TVT gets stiffer as it is stretched more.

The modulus of the implant shown in figure 1 and described herein was found to be 0.14N/% at 10%, 0.15N/% at 20% and 0.17n/% at 30%. The implant of the present invention is therefore around twice as stiff as TVT and extension is more linear.

Referring to figure 3, in a further embodiment the medical implant is a substantially flat tape 2 in which a supporting portion or zone 4 is interposed between two fixing portions or zones 6 and two resilient portions or zones 8.

The fixing zones 6 are discrete zones of fixation extending from the resilient zones 8 to a first 10 and second 12 end of the tape. The resilient zones 8 are interposed between the supporting zone 4 and one of each of the fixing zones 6.

The resilient zone as shown in figure 3 is approximately 1 cm in length, but depending on the type of implant and the geometric design of the resilient zone used, the amount of extension of the implant required together with the micro material properties of the implant, the resilient zone can be of different dimensions.

The properties of the resilient zone in the medical implant, for example the force required to promote extension and the elasticity etc, can be determined by the geometric design of a portion of the implant and / or the micro material design used for a portion of the medical implant. In figures 1 to 3 the resilience of the resilient zone is determined by a combination of a geometric and micromaterial design features.

As shown in figure 3, the resilient zone comprises elongate strip portions of material located between the supporting zone and fixing zone of the implant.

These strip portions, when not under tension, are bowshaped and are arranged such that they form a series of alternate and side by side convex and concave elongate strips of material. The strips of material are conjoined from the supporting zone to the fixing zone.

On application of an extending force of up to 3N to the tape along its length, the bowshaped portions of the tape are pulled into straight strips, the ends of the bowshaped strips being brought or pulled together, enabling extension of the tape by 2-3 mm. The movement of the strips of tape from the resting bowshape into the tensioned straight strips of tape allows the tape to resiliently extend along its length.

The maximum length to which the tape can be extended is achieved when the convex and concave portions of the tape are pulled such that these strips are brought into alignment with the longitudinal axis of the implant.

On release of the extending force these now straightened strips of tape of the resilient zone return to their bowshape causing the tape to resiliently return to its non-extended length.

The ability of the tape, in use, to show resilient extension following the application of an extending force means that the tape more accurately mimics the movement of dynamic bodily tissue.

In order that the bowshape like portions of the tape can be pulled such that they are straightened, the material of the tape must be resilient to an extent. The amount of resilience of the material will affect the resilience of the tape to an extending force.

The inclusion of the resilient zones within the medical implant shown in figure 1 provides some tolerance in the location of the implant under the urethra, to suitably support the urethra during periods of increased abdominal pressure, without causing damage and / or discomfort. There is less chance of the implant therefore being incorrectly placed in the body. Thus the resilient zone of the implant means that the implant supports the urethra in a more similar manner to that of dynamic bodily tissue. The implant therefore facilitates repair of tissues which in use surround the implant and / or the implant provides support or replaces weakened muscles or tissues.

With reference to figure 2, a second embodiment of the present invention is shown in which the medical implant is for use in fascia repair.

A difficulty in using a medical implant in the repair of fascia is that the implant must be secured

around the defect such that tissues cannot protrude through the defect. However, the implant should not pull on the tissues and / or fascia surrounding the defect too much, particularly during times of increased pressure. If at rest or during periods of increased pressure the implant pulls too much on the tissues around the defect, the implant or surrounding tissue may become damaged or torn.

As shown in figures 2A and 2B, a resilient zone may be provided in a portion of an implant used in the repair of fascia such that the implant may more accurately mimic the properties of the dynamic bodily tissues of the abdominal wall. In particular, the inclusion of a resilient zone in the material of the implant for tissue repair provides the implant with dynamic properties in particularly defined directions. The implant is therefore more similar to the tissues of the abdominal wall. As the implants described by the present Application have a degree of resilience or elasticity, then use of such implants to patch an opening in the abdominal wall has the advantage that the patient is less likely to suffer trauma and there is less chance of damage to the surrounding tissues at periods of increased abdominal pressure.

As shown in figure 2A, the resilient zone 20 may be provided around the perimeter 22 of the implant 18 allowing a degree of resilient extension of the implant in any direction.

The degree of resilient movement of the implant is determined by the size, geometric design or micro-material design of the resilient zone. Thus the implant can be adapted such that it accurately mimics the dynamic properties of the tissue which it is being used to facilitate the repair of, or provide support to.

Alternatively, as shown in figure 2B, particular portions of the implant 30 may include a resilient zone 32 therefore limiting the resilient extension of the implant 30 to particularly defined directions and areas of the material of the implant.

This may be of particular benefit if it is only appropriate for elasticity or resilience of the implant to be present in a defined direction or location.

It can be appreciated that the degree of resilient movement of the implant can be adjusted by altering the size, geometric design or micro material design, including materials and material construction of the implant in the resilient zone, such that the implant more accurately mimics the dynamic properties of the tissue in which it has been used to repair or which it is providing support.

As a further example, an implant comprising a resilient zone may be used in prolapse repair or pelvic floor repair. In this case the resilient

movement of the implant would be similar to those dynamic tissues of the pelvic or vaginal area.

A variety of geometrical constructions may be used to provide a resilient zone within a particular medical implant. For example, a concertinaed arrangement may be included in which the folded material of the implant provides for the resilient displacement or elasticity of the implant in a direction substantially perpendicular to the folds of the concertina.

Alternatively there may be provided a particular micro material design dependent on the material used to construct the implant. For example, if the implant is formed from a mesh material such as prolene of polyester then a particular weave or knit may be utilised to allow extension of the material in particularly defined directions.

Claims

1. A medical implant which comprises a mesh wherein the mesh is a resilient zone which in use provides for the resilient extension of the implant.

2. A medical implant comprising a resilient zone wherein in response to forces of up to 20N the resilient zone provides for the resilient extension of the length of the implant between 1 to 60%.

3. A medical implant as claimed in claim 1 or 2 comprising a resilient zone wherein in response to forces of up to 20N the resilient zone provides for the resilient extension of the length of the implant between 5 to 40%.

4. A medical implant as claimed in any preceding claim wherein the resilient zone provides resilient extension to the implant in one defined direction.

5. A medical implant as claimed in any preceding claim wherein the resilient zone provides resilient extension to the implant in a plurality of defined directions.

6. A medical implant as claimed in any preceding claim wherein the resilient zone of the implant is capable of allowing the resilient extension of at least a portion of the implant due to its geometric design.

7. A medical implant as claimed in any preceding claim comprising tape means including at least one suspensory portion and at least one support portion wherein the resilient zone is located in the support portion of the tape.

8. Use of an implant as claimed in any preceding claim as a curative response to failure of fascia or soft tissue failure such as supporting the urethra, treating urinary incontinence, uterovaginal prolapse, inguinal, incisional or other abdominal wall hernia.

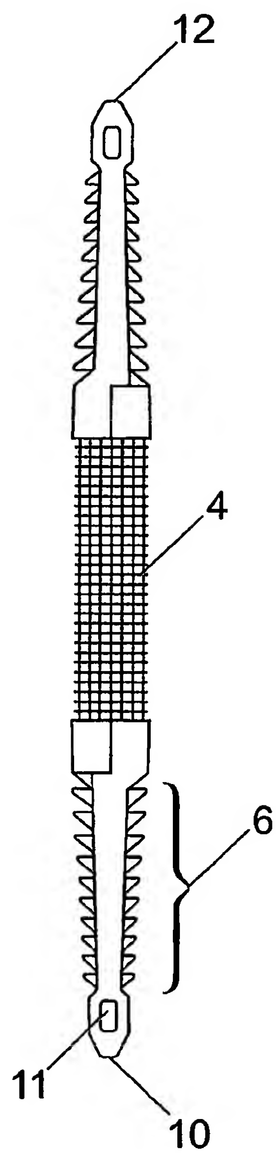


Fig. 1b

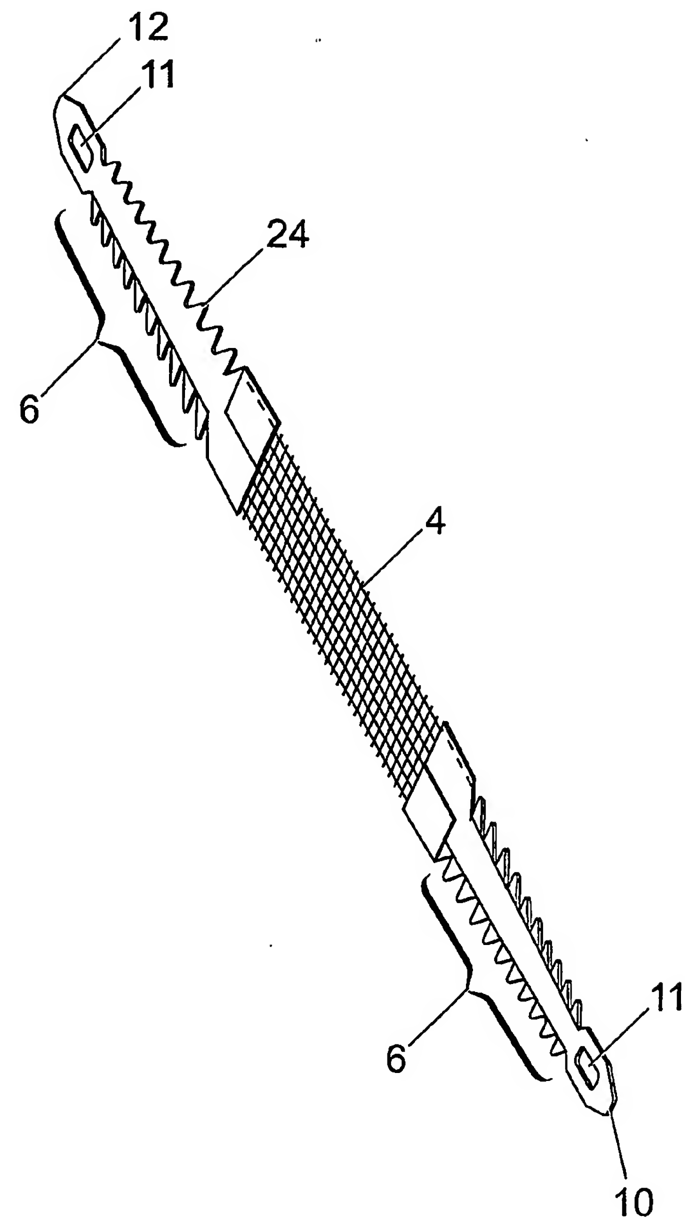


Fig. 1a

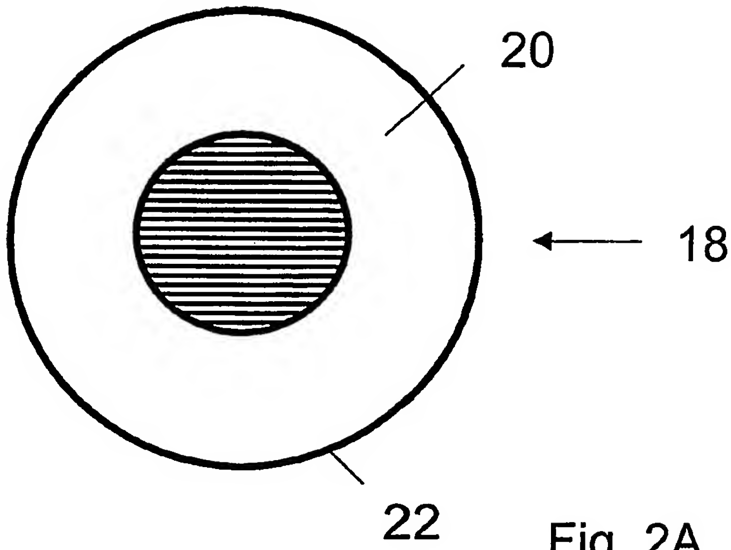


Fig. 2A

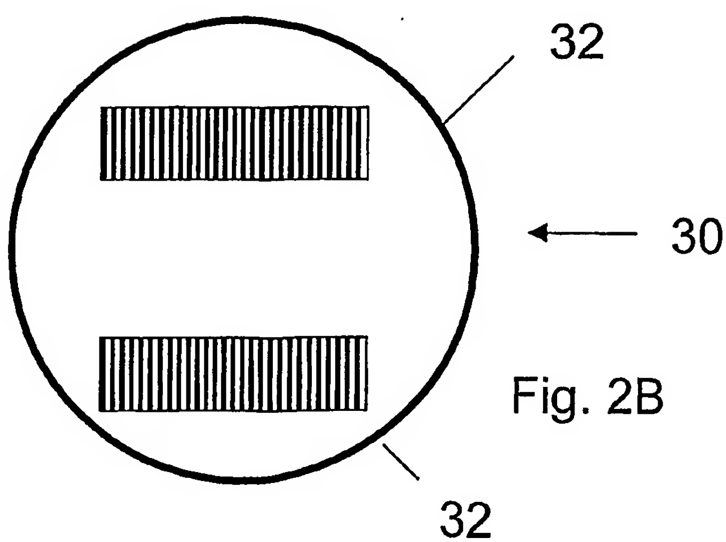


Fig. 2B

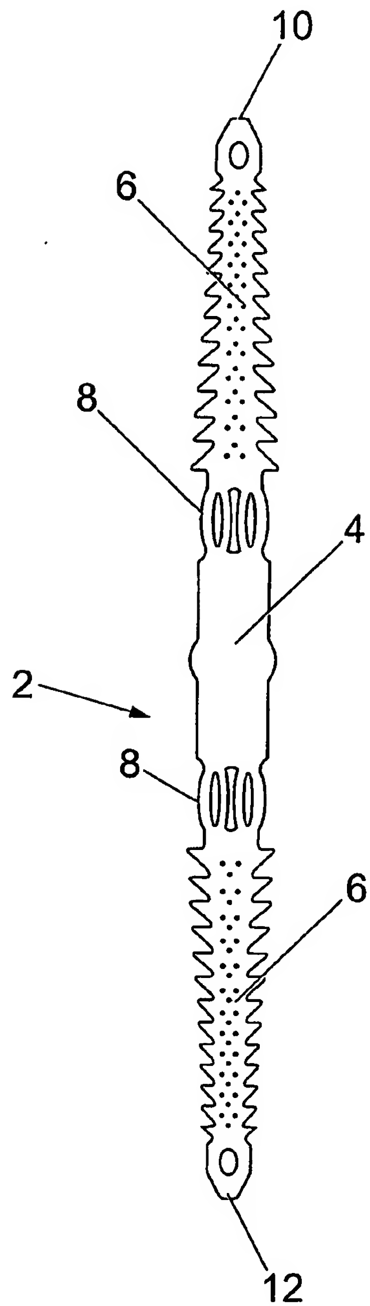
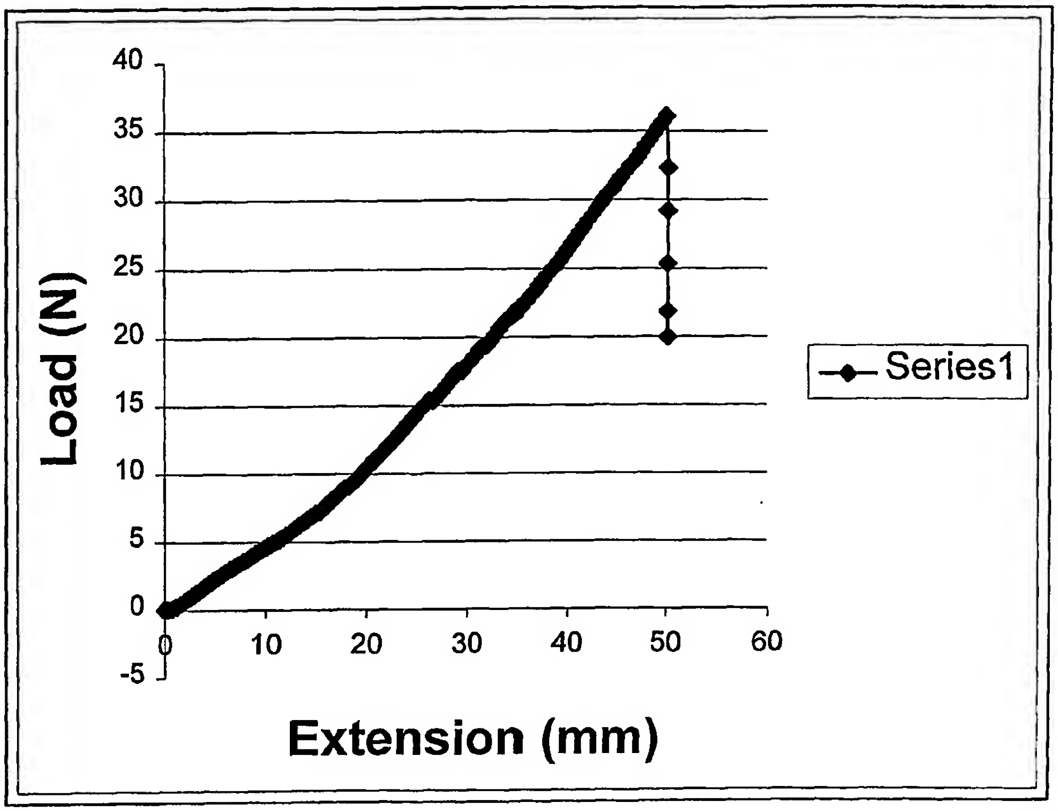
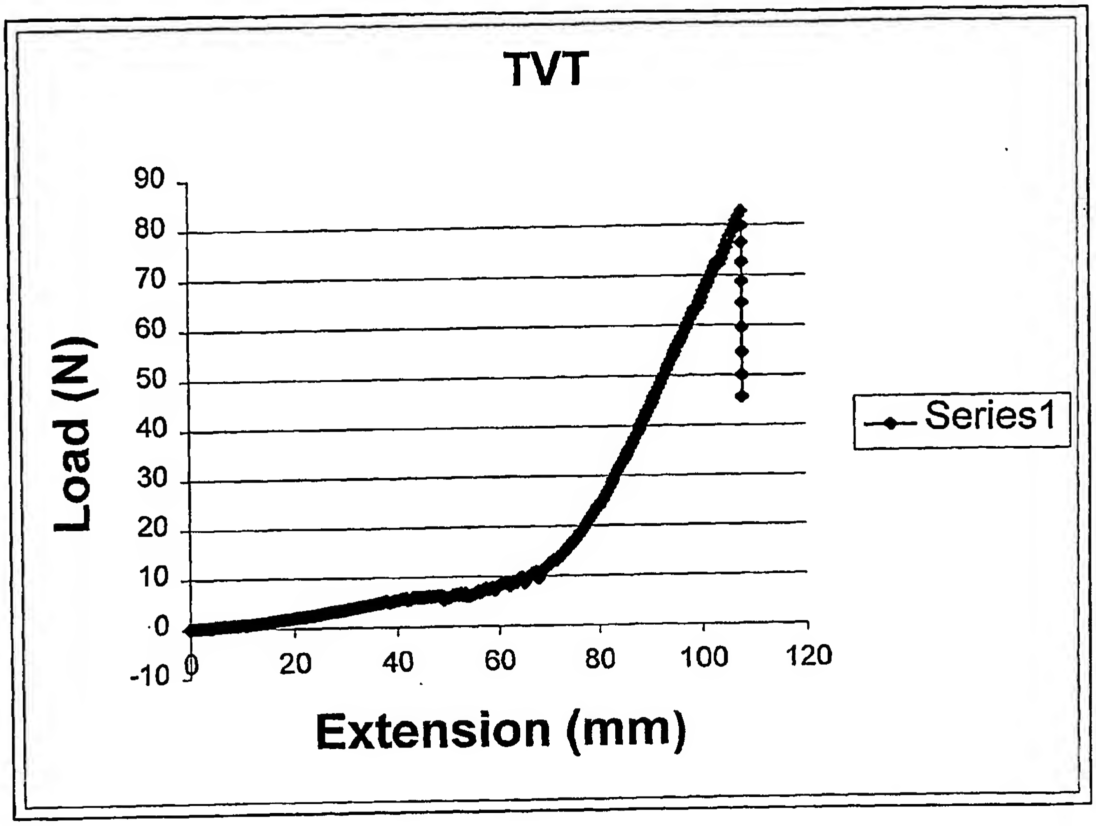


Fig. 3



40
35
30
25
20
15
10
5
0
-5
Load (N)
0
10
20
30
40
50
60
Extension (mm)
Series1

Fig. 4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Load (N)
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80
70
60
50
40
30
20
10
0
-10
0
20
40
60
80
100
120
Extension (mm)
Series1

Fig. 5

INTERNATIONAL SEARCH REPORT

Int. onal Application No
PCT/GB 03/02888

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 922 026 A (CHIN ALBERT K) 13 July 1999 (1999-07-13) column 2, line 31 -column 4, line 17 ---	1,4-7
P,X	WO 03 002027 A (FIERRO EDUARDO ;PROMEDON (FR)) 9 January 2003 (2003-01-09) page 11, line 6 -page 12, line 31 ---	1,4-7
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X	US 2002/049503 A1 (MILBOCKER MICHAEL) 25 April 2002 (2002-04-25) paragraph ‘0060! - paragraph ‘0074! ---	1,4-6
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 September 2003	02/10/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Mary, C

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 02 098340 A (KIMBERLY CLARK CO) 12 December 2002 (2002-12-12) page 5, line 21 -page 8, line 7	1,4-7
P,X	WO 03 013392 A (ODERMATT ERICH K ;AESCULAP AG & CO KG (DE); GOLDMANN HELMUT (DE);) 20 February 2003 (2003-02-20) page 16, line 13 -page 27, line 29	1,4-7
P,X	US 6 527 802 B1 (MAYER DAVID W) 4 March 2003 (2003-03-04) column 5, line 1 -column 12, line 41	1,4-6

International application No.
PCT/GB 03/02888

INTERNATIONAL SEARCH REPORT

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 8
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [X] Claims Nos.: 2,3
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 2,3

Present claims 2, 3 relate to a product defined by reference to the following parameter(s):
P1: Forces up to 20N

P2: Extension of the length of the implant between 1 to 60%
The use of these parameters in the present context is considered to lead to a lack of clarity within the meaning of Article 6 PCT. It is impossible to compare the parameters the applicant has chosen to employ with what is set out in the prior art. The lack of clarity is such as to render a meaningful complete search impossible.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Int onal Application No
PCT/GB 03/02888

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